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The Manager  
Dockets Management Branch - HFA 305  
Food & Drug Administration  
5680 Fishers Lane Rm 1061  
Rockville Md 20852  
U.S.A.

- Dear Sir/Madam

**DOCKET 98P 0683 – FOOD LABELLING HEALTH CLAIMS:  
SOY PROTEIN AND CORONARY HEART DISEASE**

I note your publication at pages 45932-45937, August 23, 1999, Vol.64 #1621 of the Federal Register. I believe it is improper to allow only 30 days for submissions. The law requires 60 days, and this is even more difficult as it is summer vacation time.

I would like to address two of the statements in that notice:

1. "When Congress enacted the 1990 amendments, it sought to ensure that the rules pertaining to health and nutrient content claims would be enforceable (see H.Rept.538, 101<sup>st</sup> Cong., 2d sess. 8,9 (1990) ). Health and nutrient content claims are intended to make the consumer aware of the nutritional attributes of the labelled food. Because these claims are meant to help consumers maintain healthful dietary practices, it is of the utmost importance that they accurately reflect the nutritional composition of the labelled food. (See 136 Congressional Record, H12953, October 26, 1990, statement of house floor managers: "There is a great potential for defrauding consumers if food is sold that contains inaccurate or unsupportable health claims." **(emphasis added)**)
2. "Ensuring the accuracy of claims was an overriding concern of Congress in passing the 1990 amendments. Congress envisioned that, under the Act as amended, . . . "only truthful claims may be made on foods" (136 Congressional Record H12953, October 26, 1990, statement of Representative Waxman).

A manufacturer who places a health or nutrient content claim in food labelling must have knowledge that the food qualifies to bear the claim, Congress expected that manufacturers would have to ascertain the nutritional attributes of their food products, through laboratory analysis or otherwise, in order to label those products properly. FDA has stated previously that a food manufacturer is responsible for the accuracy of its food labels (38 FR 2079 at 2163 and 2165). Indeed, a claim in food labelling that calls the consumer's attention to the food's nutritional characteristics is a representation that the manufacturer has evidence that the food meets the requirements for the claim. Thus, making a claim without such a basis would be misleading, in violation of section 403(a) of the Act." **(emphasis added)**

An integral content of soy protein are the isoflavones.

Food and Drug Administration experts have, in the past, addressed the toxic effects of the isoflavone chemicals found in soy protein. Here are their opinions:

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1. Dr Michael Bolger, Risk Assessor, Washington Office:  
Reproductive failure;  
Uterine hypertrophy;  
Infertility;  
Impaired reproduction.  
His report is dated September 3, 1997.
2. Dr D.M. Sheehan, FDA Senior Reproductive and Genetic Toxicologist Jefferson, Arkansas:  
Toxicity in the thyroid;  
Toxicity in tissues sensitive to estrogen;  
Risk of abnormal brain development;  
Risk of breast cancer;  
Evidence of thyroid abnormalities;  
Evidence of Autoimmune Diseases: Thyroiditis and Type 1 Diabetes;  
Evidence of brain atrophy;  
Evidence of dementia.  
Report dated February 19, 1999.
3. Also, the Australia/New Zealand Food Authority (A.N.Z.F.A.) has assessed potential risks in a March 1999 Assessment. Excerpt from page 19:  
  
"Phytoestrogens appear to be able to interfere with the thyroid hormone homeostasis in adults and in infants. In normal individuals this effect may be compensated by the existing homeostatic mechanisms, but for individuals in whom iodine intake is low or the thyroid function is compromised, phytoestrogens are a potential hazard."
4. The Life Sciences (FASEB) Evaluation of Soy Protein as a Human Foodstuff (SCOGS – 101) of August 1979 found that the risk of nitrosamine formation in the processing of soy protein posed a health hazard. G.R.A.S. determination was withheld. In February 1999, Dr D.M. Sheehan, in his letter cited above, called for complete safety studies of soy protein. It is imperative that these studies be done before any health claims petitions can be granted.

I draw your attention to the Home Page introduction of the F.D.A.'s own Internet Site:

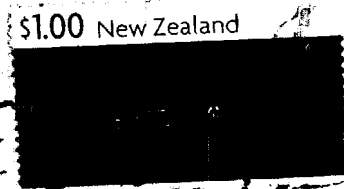
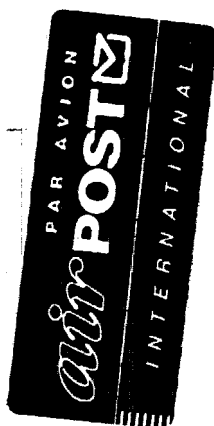
"The Nation's Foremost Consumer Protection Agency".

The mandated duty of the F.D.A. is consumer protection as its first priority. Approval of dubious health claims is a distant second. In the light of the opinions of the F.D.A.'s own highly qualified experts, it is unlikely that a Federal Court would view the approval of these claims as a legitimate exercise of that primary duty.

Yours sincerely



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